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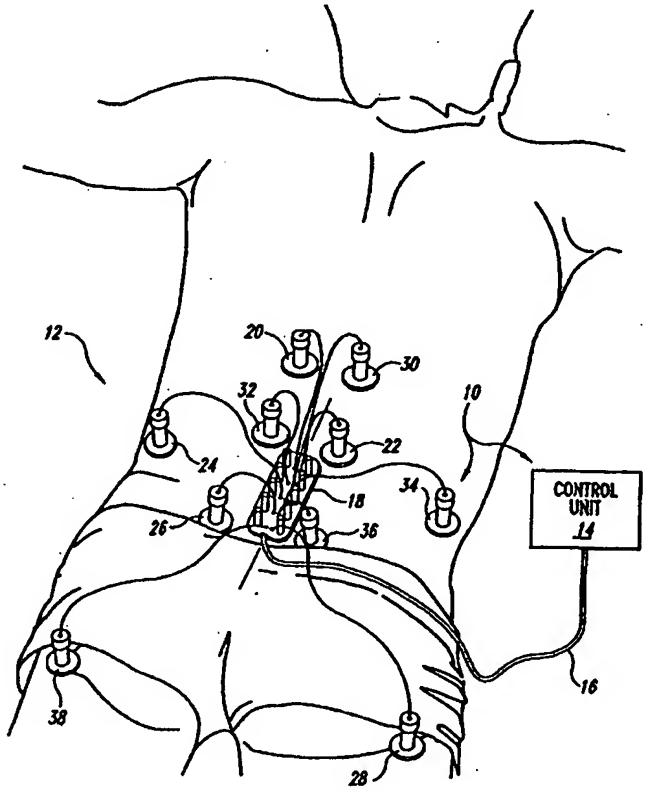
(54) Title: SYSTEM AND METHOD FOR VARYING CHARACTERISTICS OF ELECTRICAL THERAPY



(57) Abstract: A system and method for providing electrical nerve stimulation therapy to a recipient. A system in accordance with one embodiment to the invention can include electrode means (such as a percutaneous electrode) coupleable to a recipient. The system can further included signal generating means for applying an electrical signal to the electrode means. The signal generating means can include frequency varying means for applying the electrical signal to the electrode means at a plurality of frequencies.

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SYSTEM AND METHOD FOR VARYING CHARACTERISTICS OF ELECTRICAL THERAPY

FIELD OF THE INVENTION

The present invention is generally directed to a system and method for varying characteristics of electrical signals for nerve stimulation therapy.

BACKGROUND

Electrical therapy has long been used in medicine to treat pain and other conditions. One such therapy is transcutaneous electrical nerve stimulation (TENS). This therapy involves the delivery of electrical energy through patch electrodes placed on the surface of a patient's skin to treat pain in tissue beneath and around the location of the patch electrodes. The electrical energy is typically delivered to the patient in a waveform that varies according to a single preset frequency or a limited frequency combination. For example, some conventional TENS devices can provide a signal that oscillates in a single step between a high frequency and a low frequency.

The relationship between waveform frequency and efficacy varies from patient to patient and from condition to condition. Previous TENS studies therefore vary greatly in their conclusions regarding the efficacy of different TENS waveforms. For example, a review of 46 published TENS studies showed a wide variation in pain relief effect. It is difficult (if not impossible) to determine from these studies which waveform frequency should be used to treat a new patient or a prior patient with a new condition.

Some studies have attempted to determine the relationship between waveform frequency and the mechanism underlying the therapeutic effect, such as pain relief. For example, one study of 37 patients determined that TENS applied at a relatively low frequency (2 Hz) increased the concentration of an enkaphalin pain reliever in patients' cerebral spinal fluid (CSF), while TENS applied at a relatively high frequency (100 Hz) increased the concentration of a dynorphin pain reliever in the CSF. These studies did not attempt to correlate the increased concentrations

of these substances in the CSF with pain relief effect, nor did they suggest which patients would benefit more from one frequency or the other or which conditions were best treated at one frequency or the other.

Electrical therapy to treat pain and other conditions may also be delivered percutaneously. This percutaneous approach is commonly referred to as Percutaneous Neuromodulation Therapy (PNT) or Percutaneous Electrical Nerve Stimulation (PENS). Like the TENS studies, however, published studies describing percutaneous electrical therapy have focused on limited patient populations and on limited frequencies and frequency combinations. These studies do not guide clinicians in the treatment of any particular patient with unknown electrical therapy response characteristics and an unknown condition underlying the apparent symptoms.

Thus, a significant drawback of conventional electrical therapy approaches is that they fail to provide a therapeutic regimen that will be efficacious across entire populations of patients and across a variety of patient conditions. For example, some conventional approaches require trial and error testing of the patient to determine which waveform frequency would be best to treat that patient's condition, thereby consuming scarce medical personnel time and delaying the possible therapeutic effect for the patient. Furthermore, conventional electrical therapy systems take a "one size fits all" treatment approach with widely varying results.

SUMMARY

The present invention is directed toward systems and methods for delivering electrical therapy to a recipient. In one aspect of the invention, the system can include electrode means (such as a percutaneous probe) that are couplable to the recipient (for example by insertion). The system can further include a signal generating means for applying an electrical signal between the electrode means and the recipient's body. The signal generating means can include frequency varying means for applying the signal to the electrode means and have a plurality of frequencies.

In a further aspect of the invention, the frequencies provided by the system can automatically vary over a range having a minimum frequency of at

most about 20 Hz and a maximum frequency of about 40 Hz. In a further aspect of the invention, the frequency varying means can be configured to vary a frequency of electrical pulses transmitted to the electrode means from the first value of no more than about 4 Hz to a second value of no less than about 10 Hz and back to the first value over a period of time greater than 6 seconds during a therapy session.

The invention is also directed to a method for providing electrical therapy to a recipient that includes coupling an electrode to a recipient, applying electrical pulses to the electrode, and varying a frequency of the electrical pulses to the electrode while the electrode is coupled to the recipient. In a further aspect of the invention, the method can include compensating the electrical signal for changes in frequency of the electrical signal. For example, the method can include compensating an amplitude of the electrical signal in inverse relation to the log of the frequency of the electrical signal.

In still a further aspect of the invention, the method can include gradually changing the frequency of the electrical pulses from about 4 Hz to about 10 Hz over an approximately 7 second interval. The method can further include maintaining the frequency at about 4 Hz for about 10 seconds before changing the frequency from about 4 Hz to about 10 Hz. The method can further include maintaining the frequency at about 10 Hz for about 10 seconds after changing the frequency from about 4 Hz to about 10 Hz. The method can still further include changing the frequency from about 10 Hz to about 4 Hz over an approximately 6 second interval.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a montage of electrodes and a control unit for treating low back pain of a patient with electrical therapy in accordance with an embodiment of the present invention.

Figure 2 is a schematic block diagram of the control unit of Figure 1.

Figure 3 is a more detailed schematic representation of a microprocessor of the control unit of Figure 2.

Figure 4 is a waveform illustrating a therapy session including one complete cycle or period of an electrical signal which may be applied to the electrodes of Figure 1 in accordance with an embodiment of the invention.

Figure 5 is a plot of electrical signal frequency as a function of time illustrating the manner in which the frequency of the electrical signal may be varied in accordance with an embodiment of the present invention.

Figure 6 is a plot illustrating the manner in which the electrical signal pulse amplitude may be varied with electrical signal frequency in accordance with an embodiment of the invention.

Figure 7 is a plot illustrating the resulting electrical signal pulse amplitude as a function of time when the electrical signal pulse amplitude is varied with frequency as illustrated in Figure 6.

Figure 8 is a plot illustrating the manner in which the electrical signal frequency may be randomly varied with time in accordance with another embodiment of the invention.

Figure 9 is a plot illustrating the resulting electrical signal pulse amplitude as a function of time when the electrical signal amplitude is varied with frequency as illustrated in Figure 6.

Figure 10 is a plot illustrating the manner in which the electrical signal pulse width may be varied with frequency in accordance with another embodiment of the invention.

Figure 11 is a flow diagram illustrating a process for controlling administration of electrical therapy in accordance with another embodiment of the invention.

Figure 12 is a flow diagram illustrating a process for automatically varying the frequency with which electrical pulses are administered to a recipient in accordance with another embodiment of the invention.

Figure 13 is a plot illustrating the manner in which the frequency of electrical pulses delivered to a recipient can vary in accordance with an embodiment of the invention.

Figure 14 is a flow diagram illustrating a process for tracking treatment periods in accordance with another embodiment of the invention.

Figure 15 is a plot illustrating a schedule for varying the difference between a minimum frequency and a maximum frequency with which electrical pulses are administered over the course of a therapy session in accordance with another embodiment of the invention.

Figure 16 is a flow diagram illustrating a process for changing the duration of periods during a therapy session in accordance with still another embodiment of the invention.

Figure 17 is a flow diagram illustrating a process for varying the characteristics of a schedule on the basis of session time, in accordance with still another embodiment of the invention.

Figure 18 is a plot illustrating frequency change schedules for two sessions in accordance with yet another embodiment of the invention.

DETAILED DESCRIPTION

Figure 1 illustrates a system 10 for providing electrical therapy to a patient 12 in accordance with an embodiment of the invention. Here, the patient is being treated for low back pain.

The system 10 can include a plurality of electrodes or other electrical contact elements and a control unit 14. A first half of the electrodes including electrodes 20, 22, 24, 26, and 28 can form cathode electrodes, and a second half of the electrodes including electrodes 30, 32, 34, 36, and 38 can form corresponding anode electrodes. Each electrode can include a probe, such as a needle, which may be inserted into the patient's tissue for percutaneous therapy. Alternatively, each electrode can include a surface-mounted patch for transcutaneous therapy. In either embodiment, once the electrodes are placed as shown, a therapeutic electrical signal can be applied by the control unit 14 through a cable 16 and distributed between each cathode/anode electrode pair 20, 30; 22, 32; 24, 34; 26, 36; and 28, 38 by a tool tray 18. The number and placement of the electrodes and their designations as cathode or anode may be different in other embodiments.

In accordance with an embodiment of the invention, the control unit 14 can automatically vary the frequency of the electrical signal pulses applied to the electrodes over a comparatively wide range of frequencies. In one

embodiment, the frequency of the electrical pulses can vary from a minimum frequency of at most about 20 Hz to a maximum frequency of at least about 40 Hz. By varying the frequency over a range, numerous therapeutic physiologic responses can result, in direct contrast to isolated physiologic responses obtained by conventional systems through the use of a single or limited number of frequencies. Still further, because each individual therapy patient has different physiologic response characteristics as a function of applied frequency, the automatically varying frequency of the electrical signal can be effective for a large patient population not withstanding their different physiologic response characteristics. Still further, the automatically varying frequency can eliminate the aforementioned trial and error and can permit non-physician personnel to apply the therapy to each patient in a uniform manner and with effective results.

Figure 2 schematically illustrates features of the control unit 14 in accordance with an embodiment of the invention. The control unit can include an input 40, a power supply 42, an information output 44, and a pulse generator 46. The pulse generator 46 can include pulse generation hardware 48 and a microprocessor 50. The microprocessor 50 can include a memory 51, or, alternatively, the memory 51 can be external to the microprocessor 50.

As described in greater detail below, the control unit 14 can provide an electrical signal that automatically varies in frequency over a comparatively broad range of frequencies. As will also be described below, the control unit 14 may compensate or adjust characteristics of the electrical signal depending on the frequency of the electrical signal. The input 40 can provide selection of the electric signal frequency range, the manner in which the frequency is automatically varied in the selected range, and the manner in which the electrical signal is compensated. The input 40 can include a keypad in one embodiment and can include other manual or automatic input devices in other embodiments.

The power supply 42 provides suitable operating voltage to the various active components of the control unit 14. It may be of a design well known in the art.

The information output 44 may be a liquid crystal display or the like. The information output 44 may be used to display the selected frequency range,

the selected manner in which the frequency is automatically varied, and the selected manner in which the electrical signal is compensated with frequency.

The pulse generation hardware 48 may be of the type well known in the art. It provides the electrical signal under the control or direction of the microprocessor 50. The electrical signal is can include a series of biphasic pulses 52 as shown in Figure 4. Each biphasic pulse can include a consecutive pair of pulses, including a first pulse 54 of one polarity and a second pulse 56 of an opposite polarity. Alternatively, the first pulse 54 or the second pulse 56 can be eliminated, so that the pulses are of a single polarity. Each pulse 54 and 56 can have a duration D1 and D2, respectively. D1 and D2 can be on the order of 200 microseconds in one embodiment, or D1 and D2 can have other values in other embodiments. The durations D1 and D2 can be equal in one embodiment, or unequal in other embodiments. The durations D1 and D2 together define a total pulse duration TD which, as discussed below, may be varied with frequency as one manner of compensating the electrical signal.

Each of the pulses 54 and 56 also has a current amplitude A1 and A2, respectively. The amplitudes A1 and A2 may be different or equal, with a value of between about 2 and 5 milliamperes and a maximum value between about 10 and 15 milliamperes in one embodiment. As described below, the amplitudes A1 and A2 may be varied with frequency as a manner of compensating the electrical signal with frequency, in accordance with an embodiment of the invention.

The biphasic pulses are separated by an interpulse interval IPI. The IPI alone may be varied by the control unit 14 for automatically varying the frequency of the electrical signal. When the total pulse duration TD is varied to compensate the electrical signal, the IPI is then varied in concert with the TD to obtain the desired adjustments in the electrical signal frequency.

In the simplified example shown in Figure 4, the electrical signal has a pulse frequency F1 of 2 Hz for one second and a frequency F2 of 4 Hz for the next second. This two-second pattern defines a cycle or period P1 which can be repeated over the course of a therapy session S1. In other embodiments, the frequency, amplitude, durations and periods can vary in other manners over the course of the session, as will be described in greater detail below. As will also be

described below, it can be advantageous to have a period with a value of greater than 6 seconds.

Figure 3 is a more detailed schematic illustration of the microprocessor 50 described above with reference to Figure 2. In a conventional manner, the microprocessor executes operating instructions, which it can fetch from the memory 51 to provide its desired functionality in controlling the electrical signal applied to the electrodes. In doing so, the microprocessor 50 implements a plurality of functional stages, which may be divided into two groups of functional stages including frequency control stages 60 and compensator stages 70. The frequency control stages 60 can include a limits stage 62 and an interval control stage 64. The compensator stages 70 can include an amplitude control stage 72 and a pulse duration control stage 74. The amplitude control stage 72, as shown, can include substages including a current amplitude control stage 76 and a voltage amplitude control stage 78.

The limits stage 62, responsive to commands from the input 40, can set the frequency range of the electrical signal. The interval control stage 64 in turn varies the IPI automatically to automatically vary the frequency of the electrical signal. The manner in which the interval control stage 64 varies the frequency can be selectable from the input 40. For example, the frequency may be increased and decreased monotonically across the frequency range or varied randomly. The general frequency range previously referred to may be augmented so that, for example, the minimum frequency can be at most about 4 Hz while the maximum frequency can be at least 50 Hz. Alternatively, the minimum frequency can be at most 2 Hz or at most 4 Hz and the maximum frequency can be at least about 10 Hz, 15 Hz, 20 Hz or any value in between. In still further embodiments, the minimum frequency can be at most about 2 Hz while the maximum frequency can be at least about 100 Hz, or the minimum frequency can be at most about 2 Hz and the maximum frequency can be at most about 200 Hz.

The IPI between electrical pulses may be varied with each biphasic pulse or varied at less frequent intervals in a predetermined manner so that the IPI over a portion or multiple portions of the electrical signal is held constant. The IPI may be varied monotonically or randomly in a repeated manner. In one

embodiment, the IPI is varied frequently enough so that a multitude of different frequencies, (for example, at least seven), are generated during a therapy session.

The compensator stage 70 can compensate the electrical signal as the frequency changes to maintain effective signal energy for each frequency of application. With a constant total duration (TD) and amplitude, the amount of applied electrical energy per unit time and consequently the perceived intensity of the stimulation will be directly related to frequency. Hence, higher frequencies will cause more energy per unit time to be applied to the recipient than will lower frequencies. To compensate for this, and to provide effective signal energy per unit time for each applied frequency, the compensator 70, under control of input 40, may adjust the current amplitude of the electrical signal as a function of frequency with stage 76, the voltage amplitude of the electrical signal as a function of frequency with stage 78, or the total pulse duration (TD) as a function of frequency with stage 74. In one aspect of this embodiment, the amplitude and TD can be varied in an inverse relation with frequency to maintain the amount of applied energy at an approximately constant level as the pulse frequency changes.

In any of the foregoing embodiments, the microprocessor can include a schedule receiver 80 and a signal director 82 that coordinate input to the frequency control 60 and the compensator 70 and output to the pulse generation hardware 48. For example, the schedule receiver can receive information (*e.g.*, via the input 40) regarding the manner with which electrical pulses are to be scheduled during a treatment session. The signal director 82 can direct the pulse generation hardware 48 to emit electrical pulses in accordance with the received schedule.

Figure 5 illustrates a manner in which an electrical signal may be varied over time. It will be noted that during an initial time T the electrical signal frequency dwells or is held constant at an upper limit. This allows the recipient to feel a massage-like sensation for a brief period before the frequency begins to vary. Here, the frequency is decreased monotonically and then is increased monotonically. Preferably, at the end of the session, the frequency of the electrical signal pulses is once again held at the upper frequency limit for a few seconds so that the patient leaves with a positive impression.

Figure 6 illustrates how the pulse amplitude of the electrical signal represented in Figure 5 may be adjusted with frequency. The relationship illustrated is adjustment in current in accordance with the formula:

$I=C_1 - C_2 \log(F)$

wherein,

C_1 and C_2 are constants, and

F is the frequency of the electrical signal pulses.

The resulting adjusted current is illustrated in Figure 7. It is of course understood that a therapy cycle generally exceeds 10 seconds and that the frequency and amplitude pattern illustrated in Figures 5 and 7 can be repeated until the therapy session is complete.

Figure 8 shows another manner in which the frequency of the electrical signal may be varied over time. Again, the electrical signal dwells at the upper limit for an initial time T and then thereafter varies randomly within the selected frequency range. With each adjustment in frequency, the frequency, and hence the IPI is held constant for a few seconds. During each adjustment in frequency, the IPI varies monotonically between the previously selected frequency and the newly selected frequency.

Figure 9 shows the current amplitude versus time for the electrical signal represented in Figure 8 wherein the current is adjusted in accordance with the relationship to frequency as described with respect to Figure 6. Either the current amplitude or the voltage amplitude may be adjusted in this manner.

Figure 10 shows the compensation made to the electrical signal represented in Figure 5 wherein the total pulse duration (TD) (instead of the amplitude) is varied with frequency. In one embodiment, the relationship for adjustment in total pulse duration can be represented with the formula:

$TD = C_1 - C_2\sqrt{F}$

wherein,

C_1 and C_2 are constants, and

F is the frequency of the electrical signal pulses.

As those skilled in the art will appreciate, both amplitude and duration may be varied together to achieve the desired electrical signal compensation with frequency.

Many of the operations described above with reference to the foregoing embodiments and described below with respect to further embodiments can be performed manually. Alternatively, these processes can be performed automatically, for example, by a computer-based system (or microprocessor-based system), such as the one described above with reference to Figure 2. Accordingly, many of the operations can be performed as steps, routines, or subroutines of a computer program. For example, as shown in Figure 11, a process 1110 for controlling the administration of electrical therapy can include receiving an indication of the initiation of a therapy session (step 1112). In step 1114, the process can include receiving a schedule for varying the frequency of electrical pulses provided to a patient or recipient during the course of the session. In step 1116, the process can include directing the variation of the electrical pulse frequency according to the schedule received in step 1114. In step 1118, the process can include receiving an indication that the therapy session is at an end, and in 1120, the process can include directing the electrical pulses to cease.

In one aspect of an embodiment described above with reference to Figure 11, the process steps can be performed by computer software and the session initiation and termination indications (steps 1112 and 1118) can be manually input to the program by a practitioner operating the input 40 (Figure 2). Alternatively, these indications can be retrieved by the program from a database. Similarly, the step of receiving a schedule for varying the frequency of electrical pulses (step 1114) can include receiving a schedule that is input manually by a practitioner, or alternatively, the schedule can be retrieved by the software program from a database. The database can be stored in local memory (such as the memory 51 described above with reference to Figure 2) or remote memory. The database can be stored on any computer-readable medium, such as, but not limited to, magnetic and optically readable and removable computer disks, as well as media distributed electronically over the Internet or over other networks (including wireless networks).

In any of these embodiments, the software performing the steps of directing the variation of electrical pulse frequency according to the schedule (step 1116) and directing the electrical pulses to cease (step 1120) can be operatively coupled to a pulse generator (such as was described above with reference to Figure 2) to control the pulses delivered by the generator to the recipient.

Figure 12 is a flow diagram of a process 1210 for automatically varying the frequency with which electrical pulses are delivered to a recipient. In 1212, the process can include receiving a schedule for varying the frequency. The schedule can include a minimum frequency value, a maximum frequency value, pulse durations and/or IPIs for each frequency, a period over which the frequency changes from the minimum value to the maximum value and back, and a rate at which the frequency changes from the minimum value to the maximum value and back. In step 1214, the process can include directing the variation in signal frequency over the period. In step 1216, the process determines whether the period just completed is the last period of the session. If the just-completed period is not the last period, the process returns to step 1214 to direct the variation of the signal frequency over the next period. Step 1214 is repeated until the session ends.

In one aspect of this embodiment, the frequency of the electrical pulses delivered to the recipient can vary between the minimum and maximum frequencies described above with reference to Figure 3. Alternatively, the frequency of the electrical pulses can vary from a minimum frequency of about 4 Hz to a maximum frequency of about 10 Hz, as shown in the plot of Figure 13. In a further aspect of this embodiment, the electrical pulses can be delivered to the recipient at the minimum frequency for an initial interval of about ten seconds. The frequency can then be gradually increased to the maximum frequency of about 10 Hz over a time interval of about seven seconds. The electrical pulses can be delivered at the maximum frequency for a time interval of about ten seconds, and the frequency can then be decreased back to the minimum frequency over a time interval of about 6 seconds. Accordingly, the period of the frequency schedule shown in Figure 13 is about 33 seconds.

In an alternative embodiment (shown in Figure 14), the frequency of electrical pulses can vary between about 2 Hz and about 20 Hz over a period of about 50 seconds. Alternatively, the length of the period can have other values, for example, a value greater than 6 seconds, up to and including about 2 minutes. In one particular embodiment, the period can have a value of about 10 seconds. The maximum frequency (which can range from about 10 Hz to about 20 Hz in one embodiment) can be low enough to trigger the release of endorphins in the recipient, which can have a therapeutic benefit and can provide a positive sensation for the recipient. In a further alternate embodiment, the frequency does not remain constant at the beginning and end of each period, but changes constantly during the period. In any of the embodiments described above with reference to Figures 1-14, the electrical pulses can be delivered in a manner that is repeated from one period to the next until the therapy session is complete. Alternatively, the duration of the periods and/or other aspects of the schedule for each period can change throughout the course of the session, as will be described in greater detail below.

Figure 15 graphically illustrates a schedule for a 30-minute session during which the maximum and/or minimum frequency of electrical pulses delivered to the recipient during a given period varies over the course of the session, in accordance with an embodiment of the invention. In one aspect of this embodiment, the frequency is constant at the beginning and the end of the session. During an intermediate portion of the session, the frequency varies between a minimum frequency 1512a and a maximum frequency 1510. The difference between the minimum frequency 1512a and the maximum frequency 1510 can increase until the mid-point of the session (at 15 minutes in the example shown in Figure 15), then decrease until the frequency is again constant toward the end of the session.

In the embodiment shown in Figure 15, the electrical pulse frequency cycles between a constant minimum frequency 1512a of about 4 Hz and a maximum frequency 1510 that increases up to 15 Hz, then decreases. At 12.5 minutes into the therapy session, the electrical pulse frequency cycles between 4 Hz and 10 Hz. The manner in which the frequency changes from minimum to maximum at this point in the session was described above and shown in Figure 13.

The electrical pulse frequency can cycle between minimum and maximum values in a similar fashion at other points in the session.

In one aspect of this embodiment, the frequency can cycle between the maximum frequency 1510 and the constant minimum frequency 1512a. Alternatively, the frequency can cycle between the maximum frequency 1510 and a minimum frequency 1512b that first decreases and then increases. In another embodiment, the frequency can cycle between the maximum frequency 1510 and a minimum frequency 1512c that first increases then decreases.

In other embodiments, the frequency can vary over the course of the session in accordance with other schedules. For example, the minimum frequency and maximum frequency may not be the same at the beginning and end of the session, and may or may not be the same during other portions of the session. The minimum and maximum frequencies can be greater than or less than the values shown in Figure 15, and the rates at which the minimum and maximum frequencies change can be different than is shown in Figure 15. In any of these embodiments, the manner in which the frequency changes can be selected based on the effect or expected effect on a patient or group of patients.

Figure 16 is a flow chart schematically illustrating a process 1610 for tracking electrical stimulation periods during the course of a therapy session. In step 1612, the process includes receiving the duration of a given period. In step 1614, the process includes receiving a frequency change schedule for the given period. For example, the frequency change schedule can be generally similar to any of the schedules described above. In step 1616, the process includes directing the frequency variation of electrical pulses over the given period. In step 1618, the process determines whether or not the just-completed period is the last period of the session. If not, steps 1612-1618 are repeated until the end of the session.

In one aspect of this embodiment, each of the periods throughout the session can have the same duration and the same frequency change schedule. For example, each period can last 33 seconds, as described above with reference to Figure 13. Alternatively, the periods can have a different length of time, for example, any length of time greater than 6 seconds and less than about 120 seconds. In one particular embodiment, the period can have a value of at least 10

seconds. An advantage of a period having a value greater than 6 seconds is that the recipient may be more likely to relax during treatment because the rate at which the frequency changes is lower than for some conventional devices that change the frequency over a period of 6 seconds or less.

In still another alternative embodiment, the length of the period, the minimum and maximum frequencies attained during the period, the rate with which the frequencies are changed during the period, and/or the amplitude of the current and/or voltage administered to the recipient during the period may be changed over the course of a given session. For example, the length of each period may be selected in accordance with the recipient's state of mind or expected state of mind. Recipients who may be anxious toward the beginning of the session can accordingly receive therapy having initially short periods that gradually lengthen over the course of the session as the recipient relaxes. Alternatively, the periods can initially be relatively long to counteract the recipient's initial anxiety.

In a further aspect of this embodiment, the treatment process can include a biofeedback loop that automatically changes the length of the period (or other aspects of the treatment, such as pulse frequency) in accordance with changes in the recipient's physical state. For example, a signal indicating the recipient's respiration rate, heart rate, brain waves and/or diaphoretic response can be operatively coupled to the microprocessor 50 (Figure 2) in a conventional manner (for example, via the input 40) to control or affect the characteristics of the electrical pulses.

Figure 17 is a flow chart illustrating a process 1710 for varying the schedule of electrical pulses administered to the recipient based on the duration of the session during which the pulses will be administered. In step 1712, the process includes receiving a session time duration and in step 1714, the process includes determining the schedule according to which the frequency and/or other characteristics (such as the duration, amplitude and/or interpulse interval) will change during the course of the session. In one embodiment, the changes can occur in a gradual manner, for example, by a series of closely spaced step changes. Changes in frequency can be compensated for by changes in pulse total duration and/or amplitude, as described above with reference to Figures 7 and 10. The schedule can be determined by a formula, a table lookup, an input from a

practitioner, and/or by other sources. In any of these embodiments, the schedule selected for a particular session time is selected based on the session time. Accordingly, the characteristics of the schedule are correlated with the length of time available for a particular session. The process can further include directing the variation of the electrical pulse signal in accordance with the schedule (step 1716). In step 1718, the process can determine whether the just-completed session is the last session to be conducted. If further sessions are to be conducted (for example, on other recipients), steps 1712-1718 are repeated until all sessions have been complete.

Figure 18 graphically compares frequency change schedules for two sessions in accordance with an embodiment of the invention. For purposes of comparison, the maximum frequency 1510 and minimum frequency 1512b schedules described above with reference to Figure 15 for a 30-minute session are shown again in Figure 18. Also shown in Figure 18 are schedules for a maximum frequency 1810 and a minimum frequency 1812b for a 20-minute session. In one aspect of this embodiment, the peak maximum frequency 1810 can be lower than the peak maximum frequency 1510, and the lowest minimum frequency 1812b can be greater than the lowest minimum frequency 1512b. In a further aspect of this embodiment, the length of time during which the frequency remains constant (at the beginning and end of the session) can be less for the 20-minute session than for the 30-minute session.

In other embodiments, other aspects of the treatment schedule can be different for sessions having different session lengths. For example, the schedules for shorter sessions can be scaled linearly directly from the schedules for longer sessions (as shown in Figure 18) or, the sessions can differ in non-linear fashions. In one specific example, the schedule can begin with the peak maximum frequency and lowest minimum frequency and end with the maximum and minimum frequencies the same. In other embodiments, the schedules can have other arrangements. For example, the period over which the frequency varies from maximum to minimum in a 20-minute session can vary from about 10 seconds to about 30 seconds over the course of the session, and the period over which the frequency varies from maximum to minimum can vary from about 10 seconds to about 120 seconds for a 45-minute session.

As may thus be seen from the foregoing, embodiments of the invention provide new and improved systems and methods for treating a patient with electrical therapy. In accordance with certain embodiments of the invention, the frequency of the applied electrical signal can be automatically varied. Thus, an aspect of the invention can eliminate adjusting pulse frequencies for a given patient by trial and error. Further, a broad range of caregivers may use the system with minimal medical training and provide effective therapy for a large patient population.

In addition, embodiments of the invention can overcome the problem with patients becoming physiologically adapted to single or a limited number of frequencies. Still further, in addition to overcoming physiologic adaptation, embodiments of the present invention can provide a therapy that is not perceived as monotonous, a common patient perception when receiving a constant stimulus for a typical treatment session of 30 minutes.

While particular embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended to cover in the appended claims all such changes and modifications which fall within the true spirit and scope of the invention.

CLAIMS

1. A system for providing percutaneous electrical therapy to a patient having a body, the system comprising:

electrode means insertable into the patient; and

signal generating means for applying an electrical signal between the electrode means and the patient's body, the signal generating means including frequency varying means for applying the electrical signal between the electrode means and the patient's body at a plurality of frequencies that automatically vary over a range having a minimum frequency of at most about 20 Hz and having a maximum frequency of at least about 40 Hz.

2. The system of claim 1 wherein the frequency varying means includes means for applying the electrical signal between the electrode and the patient's body at a plurality of frequencies that automatically vary over a range having a minimum frequency of at most about 4 Hz and having a maximum frequency of at least about 50 Hz.

3. The system of claim 1 wherein the frequency varying means includes means for applying the electrical signal between the electrode and the patient's body at a plurality of frequencies that automatically vary over a range having a minimum frequency of at most about 2 Hz and having a maximum frequency of at least about 100 Hz.

4. The system of claim 1 wherein the frequency varying means includes means for applying the electrical signal between the electrode and the patient's body at a plurality of frequencies that automatically vary over a range of at most about 2 Hz to at least about 200 Hz.

5. The system of claim 1 wherein the plurality of frequencies comprises more than seven frequencies.

6. The system of claim 1 wherein the electrical signal comprises a plurality of pulses, each consecutive pair of pulses being separated by an interpulse interval.

7. The system of claim 6 wherein the frequency varying means varies the interpulse interval of at least a portion of the electrical signal with each pulse.

8. The system of claim 6 wherein the frequency varying means varies interpulse intervals of at least a portion of the electrical signal in a predetermined manner.

9. The system of claim 6 wherein the frequency varying means varies successive interpulse intervals of at least a portion of the electrical signal monotonically.

10. The system of claim 9 wherein the frequency varying means increases successive interpulse intervals of at least a portion of the electrical signal monotonically.

11. The system of claim 9 wherein the frequency varying means decreases successive interpulse intervals of at least a portion of the electrical signal monotonically.

12. The system of claim 6 wherein the frequency varying means randomly varies successive interpulse intervals of at least a portion of the electrical signal.

13. The system of claim 6 wherein the frequency varying means varies successive interpulse intervals of at least a portion of the electrical signal in a randomly generated and repeated manner.

14. The system of claim 6 wherein the frequency varying means maintains successive interpulse intervals of at least a portion of the electrical signal constant.

15. The system of claim 6 wherein the frequency varying means maintains successive interpulse intervals of multiple portions of the electrical signal constant.

16. The system of claim 6 wherein the pulse is a biphasic pulse.

17. The system of claim 1 further including compensating means for compensating the electrical signal for changes in frequency of the electrical signal.

18. The system of claim 17 wherein the compensating means adjusts the amplitude of the electrical signal in relation to the frequency of the electrical signal.

19. The system of claim 17 wherein the compensating means adjusts the amplitude of the electrical signal in an inverse relation to the frequency of the electrical signal.

20. The system of claim 17 wherein the compensating means adjusts the amplitude of the electrical signal in inverse relation to the log of the frequency of the electrical signal.

21. The system of claim 17 wherein the compensating means adjusts the amplitude (A) of the electrical signal in accordance with the formula:

$A=C_1 - C_2 \log(F)$

wherein,

C_1 and C_2 are constants, and

F is the frequency of the electrical signal.

22. The system of claim 17 wherein the compensating means adjusts the amplitude of the electrical signal in relation to the frequency of the electrical signal.

23. The system of claim 17 wherein the compensating means adjusts the amplitude of the voltage of the electrical signal in relation to the frequency of the electrical signal.

24. The system of claim 17 wherein the compensating means adjusts duration of pulses comprising the electrical signal.

25. The system of claim 17 wherein the compensating means adjusts the duration of the pulses in an inverse relation to the frequency of the electrical signal.

26. The system of claim 17 wherein the compensating means adjusts the duration of the pulses in inverse relation to the square root of the frequency of the electrical signal.

27. The system of claim 17 wherein the compensating means adjusts the duration of the pulses in accordance with the formula:

$$TD = C_1 - C_2\sqrt{F}$$

wherein,

C_1 and C_2 are constants, and

F is the frequency of the electrical signal.

28. A system for providing electrical therapy to a recipient, the system comprising:

electrode means applicable to the recipient; and

signal generating means for applying an electrical signal to the

electrode means, the signal generating means including frequency varying means for applying the electrical signal to the electrode means at a plurality of frequencies.

29. The system of claim 28 wherein the frequency varying means varies the frequency automatically over a range between a minimum frequency and a maximum frequency.

30. The system of claims 28 or 29 wherein the electrode means comprises a percutaneous application member to render the electrode means insertable into the patient.

31. The system of any of claims 28 to 30 wherein the signal generating means includes an electrical pulse generating means.

32. The system of claim 31 wherein the signal generating means includes a timing means for time controlling the frequency varying means and/or the pulse generating means.

33. The system of claim 28 wherein the frequency varying means is configured to vary a frequency of electrical pulses transmitted to the electrode means from a first value of no more than about 4 Hz to a second value of no less than about 10 Hz and back to the first value over a period of time greater than 6 seconds during a therapy session.

34. The system of claim 28 or 33 wherein the frequency varying means is configured to automatically change a frequency of electrical pulses transmitted to the electrode means a first value to a second value and back to the first value over a period of up to about 120 seconds.

35. The system of claim 28 wherein the frequency varying means is configured to automatically adjust a frequency of electrical pulses in response to a signal received from the recipient.

36. The system of claim 28 wherein the frequency varying means is configured to vary a frequency of electrical pulses transmitted to the electrode means over a first range of frequencies for a first period of time greater than 6 seconds during a therapy session and vary the frequency of the electrical pulses over a second range of frequencies for a second period of time approximately the same as the first period of time during the therapy session.

37. The system of claim 36 wherein the frequency varying means is configured to vary the frequency of the electrical pulses over the first range of frequencies by gradually changing the frequency from about 4 Hz to about 10 Hz over an approximately 7 second interval, and wherein the frequency varying means is further configured to maintain the frequency at about 4 Hz for about 10 seconds before changing the frequency from about 4 Hz to about 10 Hz, maintain the frequency at about 10 Hz for about 10 seconds after changing the frequency from about 4 Hz to about 10 Hz, and change the frequency from about 10 Hz to about 4 Hz over an approximately 6 second interval.

38. The system of claim 36 wherein the frequency varying means is configured the frequency of electrical pulses over the first range of frequencies for a first period of time of at least 10 seconds.

39. The system of claim 28 wherein the frequency varying means is configured to vary a frequency of electrical pulses transmitted to the electrode means over a first range of frequencies for a first time period, and vary the frequency of the electrical pulses over a second range of frequencies for a second time period different than the first time period during a therapy session.

40. The system of claim 39 wherein the frequency varying means is configured to automatically vary the frequency of the electrical pulses over the first range of frequencies and automatically vary the frequency of the electrical pulses over the second range of frequencies.

41. The system of claim 39 wherein the frequency varying means is configured to vary the frequency of the electrical pulses over the first and second time periods, at least one of which has a value greater than 6 seconds and less than or equal to approximately 120 seconds.

42. The system of claim 39, wherein the frequency varying means is configured to vary the frequency of electrical pulses from a first value of about 4 Hz or less to a second value of 10 Hz or more.

43. The system of claim 28 wherein the frequency varying means is configured to apply a pulses of a first electrical signal to an electrode means coupled to a first recipient for a first session time according to a first schedule for pulse frequency, duration and period, and apply pulses of a second electrical signal to an electrode means coupled to the first recipient or a second recipient for a second session time different than the first session time according to a second schedule for pulse frequency, duration and period, with the manner in which at least one of the frequency, duration and period varies being based on the second session time and being different for the second schedule than for the first schedule.

44. The system of claim 43 wherein the frequency varying means is configured to vary the frequency of the first schedule in a repeated pattern with each cycle of the pattern corresponding to the period.

45. The system of claim 28 wherein the frequency varying means is configured to gradually varying a peak amplitude, frequency, and/or duration of pulses of the electrical signal from a first value to a second value and back to the first value over a period of time greater than 6 seconds during a therapy session.

46. The system of claim 45 wherein the frequency varying means is configured to automatically vary a peak amplitude, frequency, and/or duration of pulses of the electrical signal.

47. The system of claim 45 wherein the frequency varying means is configured to automatically reduce an amplitude and/or duration of the pulses while automatically increasing a frequency of pulses.

48. The system of claim 28 wherein the frequency varying means is configured to receive a schedule including a first frequency value of no more than about 4 Hz, a second frequency value of no less than about 10 Hz, and a time period value, and wherein the frequency varying means is configured to direct a frequency of the electrical pulses to vary from the first frequency value to the second frequency value during the time period.

49. The system of claim 48 wherein the frequency varying means is configured to receive a schedule including a first frequency range, a second frequency range, a first time period value of greater than 6 seconds, and a second time period value approximately the same as the first time period value, and wherein the frequency varying means is configured to direct electrical pulses provided to a percutaneous electrical probe to vary over the first frequency range during the first time period and vary over the second frequency range during the second time period.

50. A method for providing electrical therapy to a recipient, comprising:

coupling an electrode to the recipient;

applying electrical pulses to the electrode; and

varying a frequency of the electrical pulses applied to the electrode while the electrode is coupled to the recipient.

51. The method of claim 50 wherein coupling the electrode to the recipient includes inserting a percutaneous electrode into the recipient.

52. The method of claim 50 wherein applying electrical pulses to the electrode includes applying electrical pulses at a plurality of frequencies that

automatically vary over a range having a minimum frequency of at most about 20 Hz and having a maximum frequency of at least about 40 Hz.

53. The method of claim 50 wherein applying electrical pulses includes applying electrical pulses with each consecutive pair of pulses being separated by an interpulse interval.

54. The method of claim 53 wherein the interpulse interval of at least a portion of the electrical signal varies with each pulse.

55. The method of claim 50 including the further step of compensating the electrical signal for changes in frequency of the electrical signal.

56. The method of claim 55 wherein compensating the electrical signal includes adjusting the amplitude of the electrical signal in relation to the frequency of the electrical signal.

57. The method of claim 56 wherein the adjusting the amplitude includes adjusting the amplitude of the electrical signal in an inverse relation to the frequency of the electrical signal.

58. The method of claim 56 wherein adjusting the amplitude further includes adjusting the amplitude of the electrical signal in inverse relation to the log of the frequency of the electrical signal.

59. The method of claim 56 wherein adjusting the amplitude includes adjusting the amplitude (A) of the electrical signal in accordance with the formula:

$A=C_1 - C_2 \log(F)$

wherein,

C_1 and C_2 are constants, and

F is the frequency of the electrical signal.

60. The method of claim 56 wherein adjusting the amplitude includes adjusting the amplitude of current of the electrical signal in relation to the frequency of the electrical signal.

61. The method of claim 56 wherein the adjusting the amplitude includes adjusting the amplitude of voltage of the electrical signal in relation to the frequency of the electrical signal.

62. The method of claim 55 wherein compensating the electrical signal includes adjusting the duration of pulses comprising the electrical signal.

63. The method of claim 62 wherein adjusting the duration includes adjusting the duration of the pulses in an inverse relation to the frequency of the electrical signal.

64. The method of claim 62 wherein the adjusting the duration includes adjusting the duration of the pulses in inverse relation to the square root of the frequency of the electrical signal.

65. The method of claim 62 wherein the adjusting the duration includes adjusting the duration of the pulses in accordance with the formula:

$$TD = C_1 - C_2\sqrt{F}$$

wherein,

C_1 and C_2 are constants, and

F is the frequency of the electrical signal.

66. The method of claim 50 wherein varying a frequency of the electrical pulses includes varying the frequency from a first value of no more than about 4 Hz to a second value of no less than about 10 Hz and back to the first value over a period of time greater than 6 seconds during a therapy session.

67. The method of claim 50 wherein varying a frequency of the electrical pulses includes:

varying the frequency over a first range of frequencies for a first period of time greater than 6 seconds during a therapy session; and

varying the frequency of the electrical pulses over a second range of frequencies for a second period of time approximately the same as the first period of time during the therapy session.

68. The method of claim 67 wherein varying the frequency over the first range of frequencies includes gradually changing the frequency from about 4 Hz to about 10 Hz over an approximately 7 second interval, and wherein the method further comprises:

maintaining the frequency at about 4 Hz for about 10 seconds before changing the frequency from about 4 Hz to about 10 Hz;

maintaining the frequency at about 10 Hz for about 10 seconds after changing the frequency from about 4 Hz to about 10 Hz; and

changing the frequency from about 10 Hz to about 4 Hz over an approximately 6 second interval.

69. The method of claim 50, further comprising:

varying a frequency of the electrical pulses over a first range of frequencies for a first time period; and

varying the frequency of the electrical pulses over a second range of frequencies for a second time period different than the first time period during a therapy session.

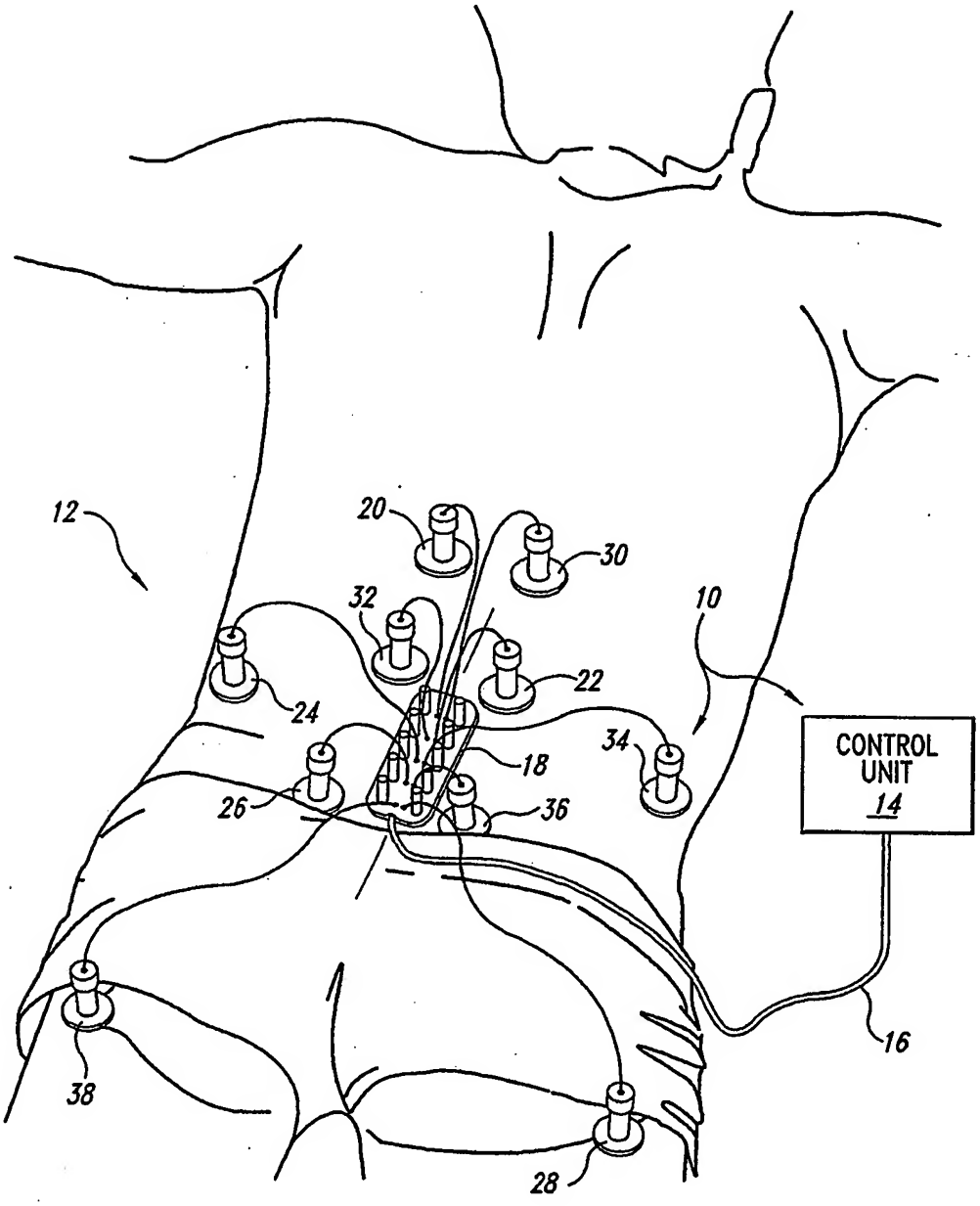


Fig. 1

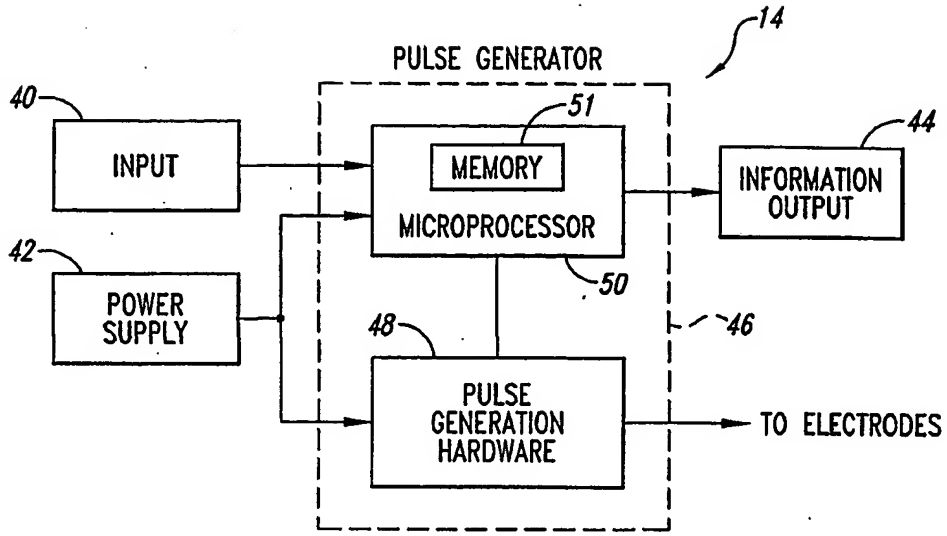

14
PULSE GENERATOR
40
INPUT
51
MEMORY
MICROPROCESSOR
44
INFORMATION OUTPUT
42
POWER SUPPLY
50
48
46
PULSE GENERATION HARDWARE
TO ELECTRODES

Fig. 2

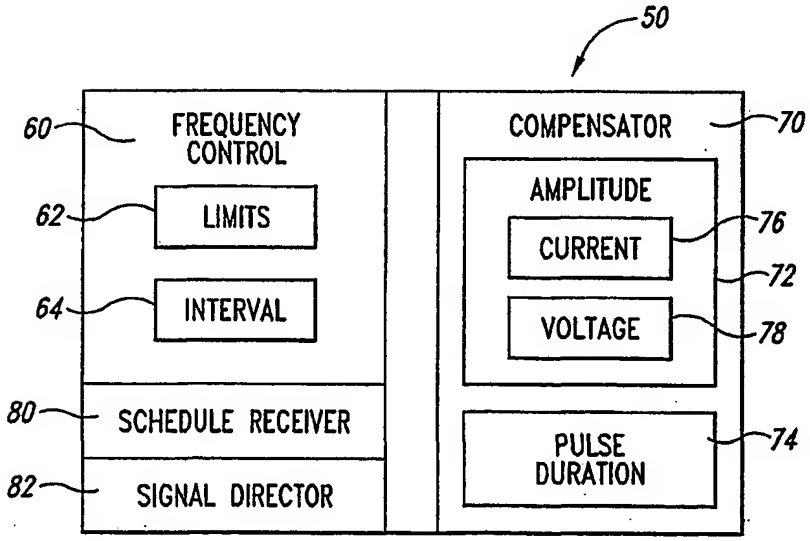

50
60
FREQUENCY CONTROL
62
LIMITS
64
INTERVAL
80
SCHEDULE RECEIVER
82
SIGNAL DIRECTOR
COMPENSATOR
70
AMPLITUDE
76
CURRENT
72
VOLTAGE
78
PULSE DURATION
74

Fig. 3

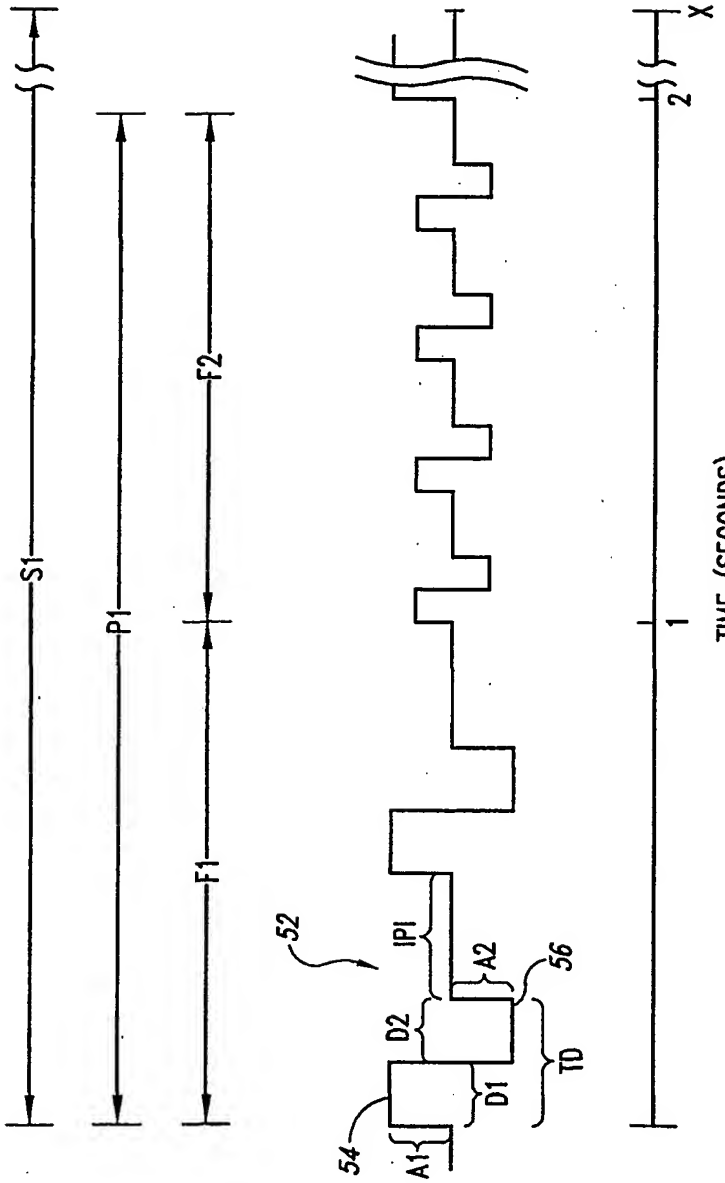
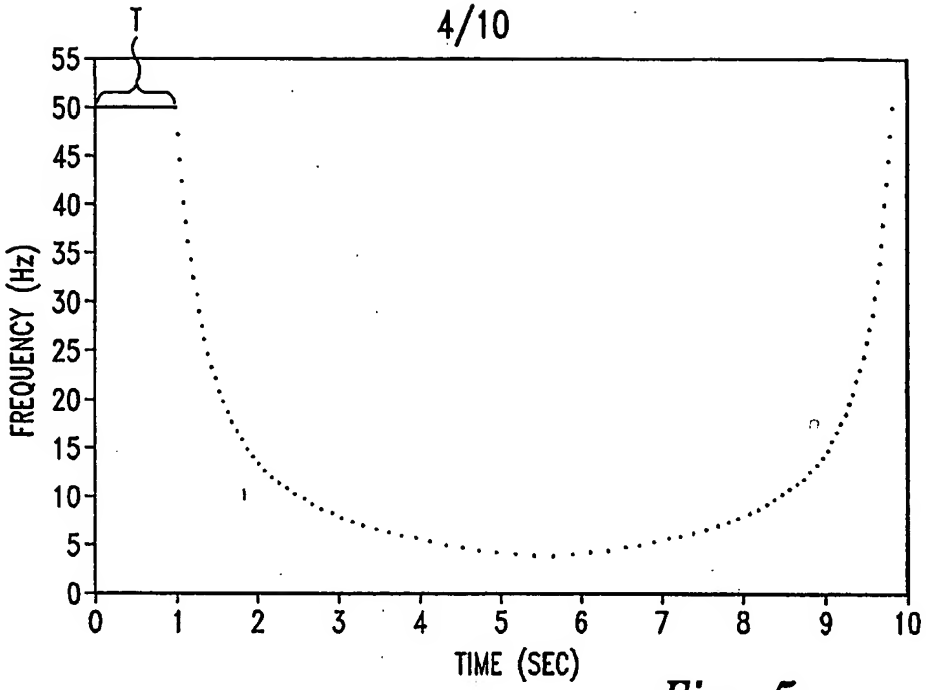


Fig. 4


T
55
50
45
40
35
30
25
20
15
10
5
0
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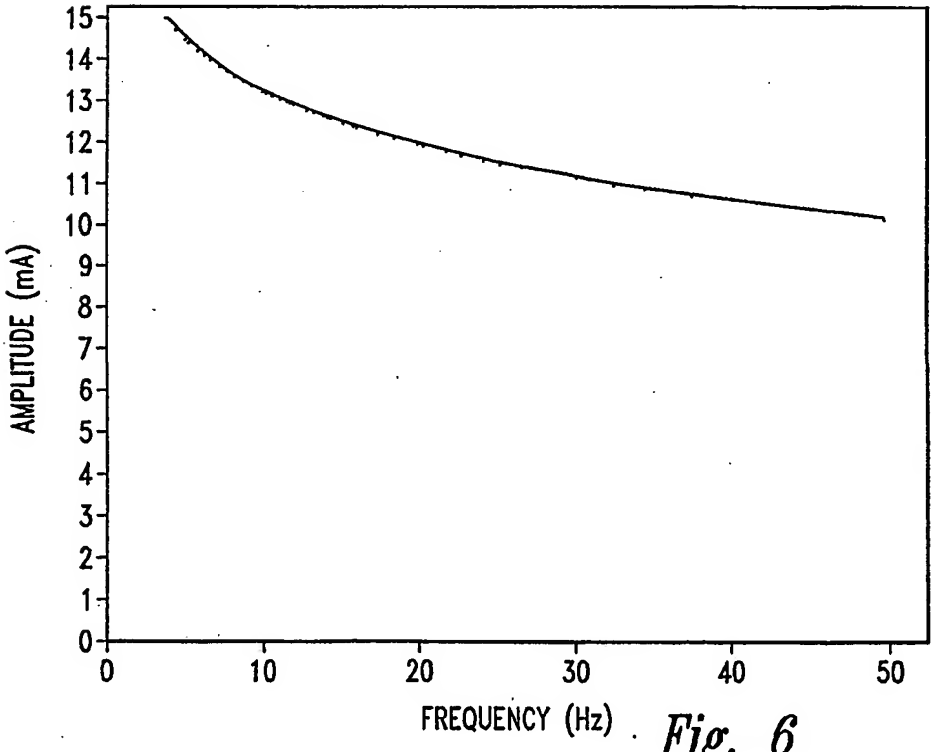
2
3
4
5
6
7
8
9
10
TIME (SEC)

Fig. 5


15
14
13
12
11
10
9
8
7
6
5
4
3
2
1
0
AMPLITUDE (mA)
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10
20
30
40
50
FREQUENCY (Hz)

Fig. 6

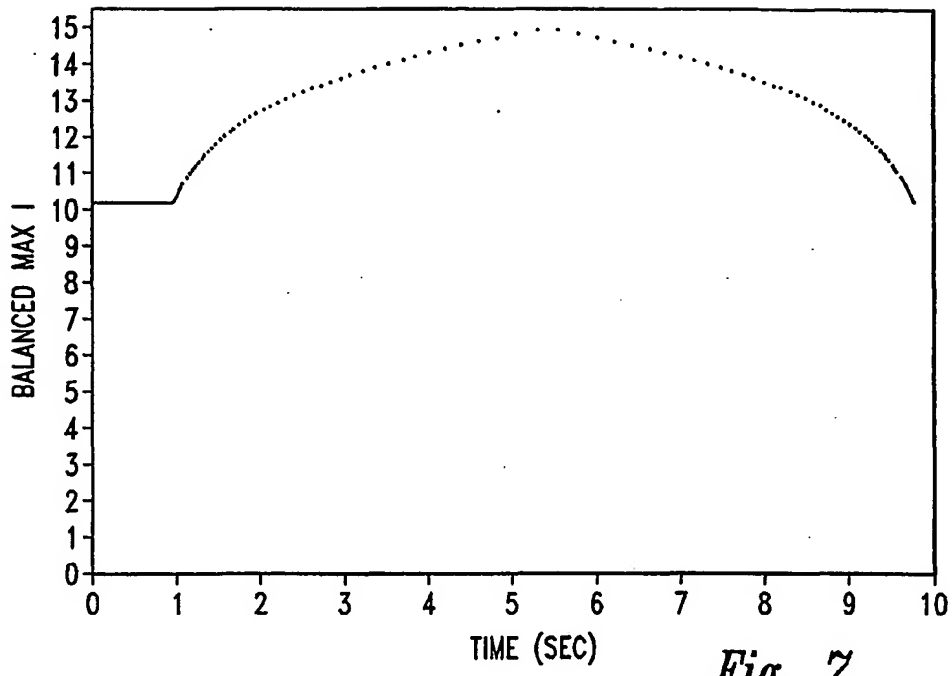

BALANCED MAX I
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
0
1
2
3
4
5
6
7
8
9
10
TIME (SEC)

Fig. 7

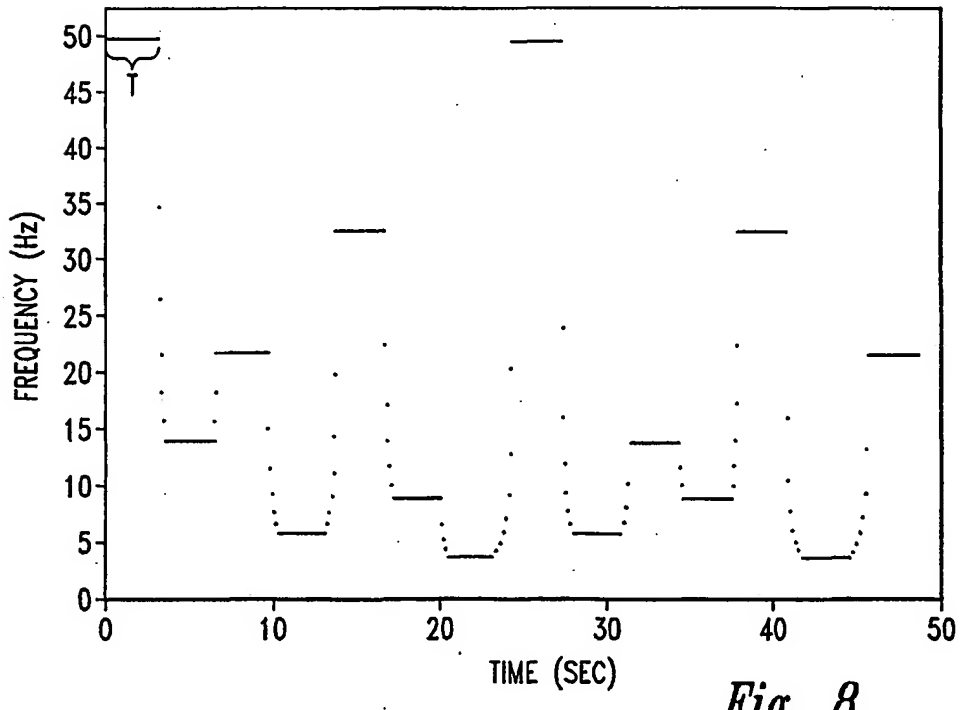
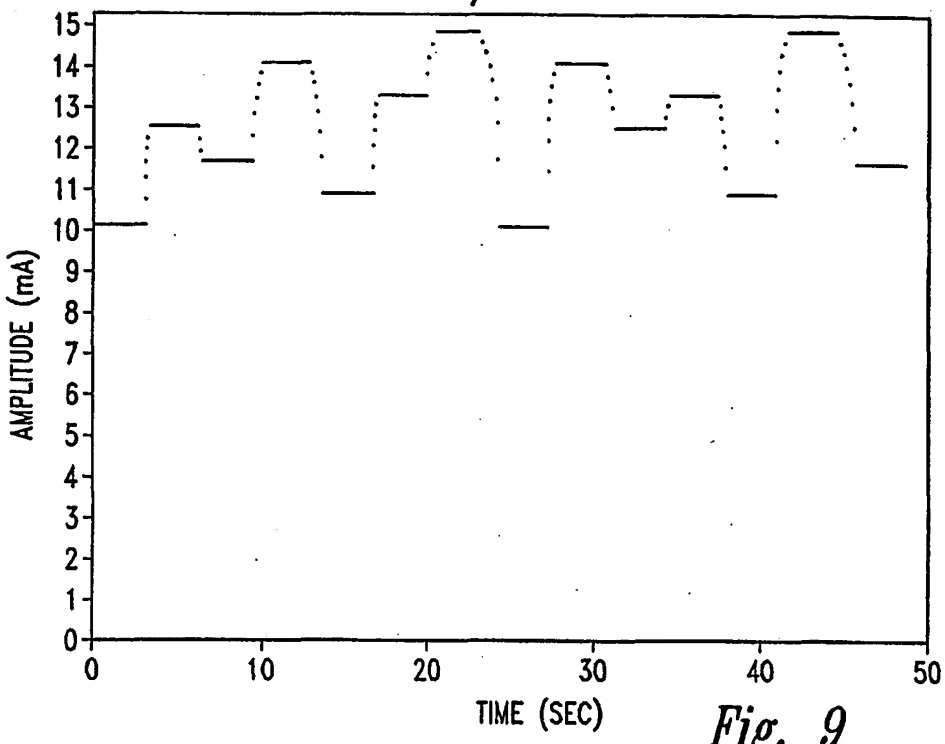

FREQUENCY (Hz)
T
0
5
10
15
20
25
30
35
40
45
50
0
10
20
30
40
50
TIME (SEC)

Fig. 8


AMPLITUDE (mA)
0
1
2
3
4
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6
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9
10
11
12
13
14
15
0
10
20
30
40
50
TIME (SEC)

Fig. 9

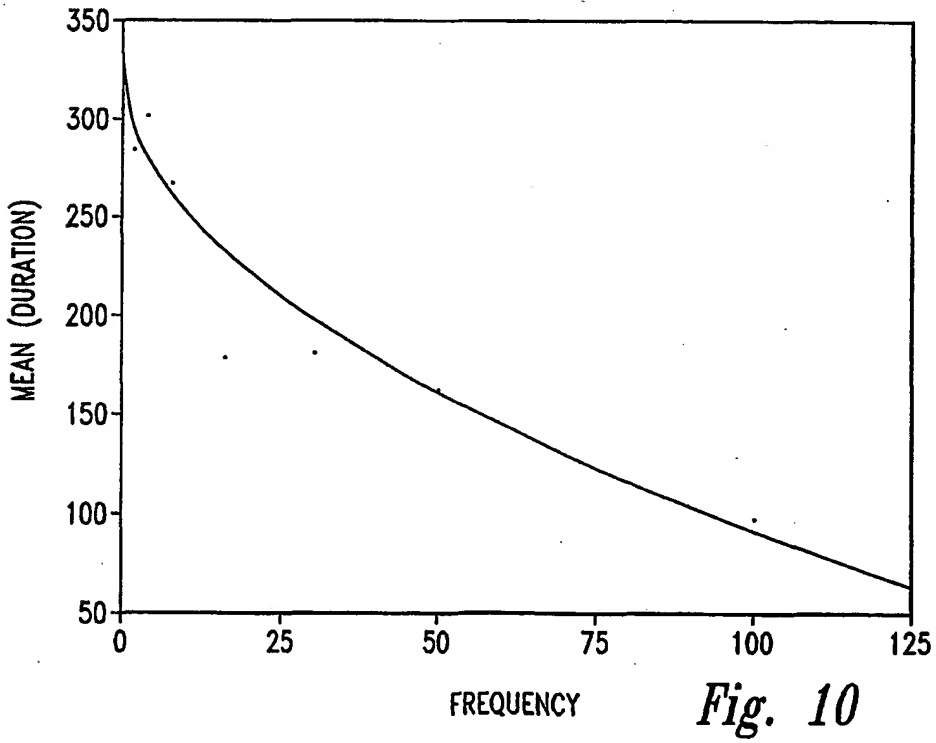

MEAN (DURATION)
350
300
250
200
150
100
50
0
25
50
75
100
125
FREQUENCY

Fig. 10

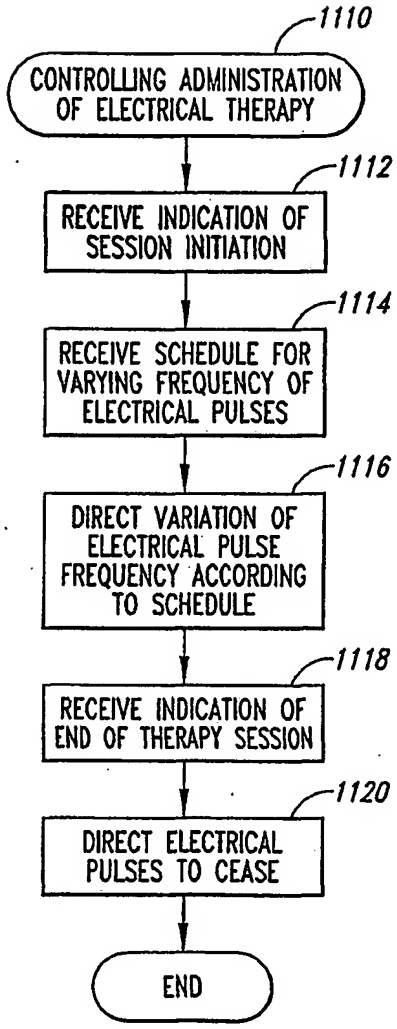

1110
CONTROLLING ADMINISTRATION OF ELECTRICAL THERAPY
1112
RECEIVE INDICATION OF SESSION INITIATION
1114
RECEIVE SCHEDULE FOR VARYING FREQUENCY OF ELECTRICAL PULSES
1116
DIRECT VARIATION OF ELECTRICAL PULSE FREQUENCY ACCORDING TO SCHEDULE
1118
RECEIVE INDICATION OF END OF THERAPY SESSION
1120
DIRECT ELECTRICAL PULSES TO CEASE
END

Fig. 11

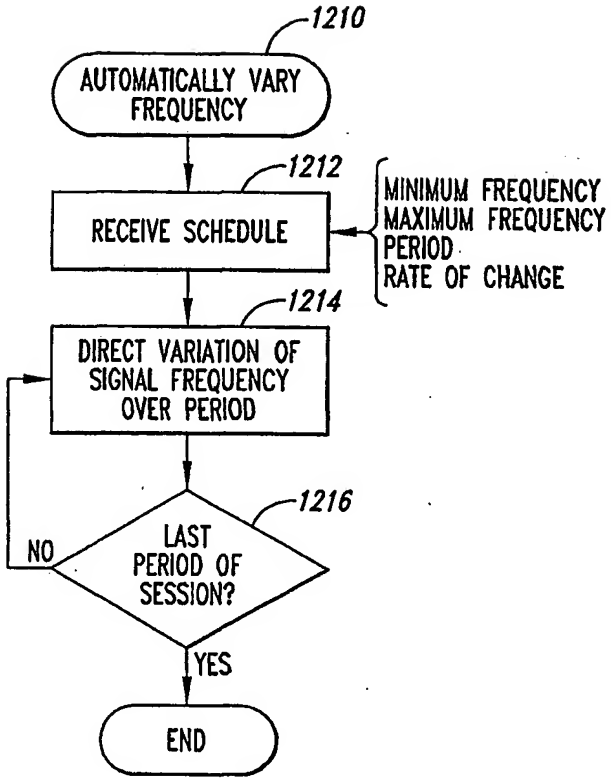
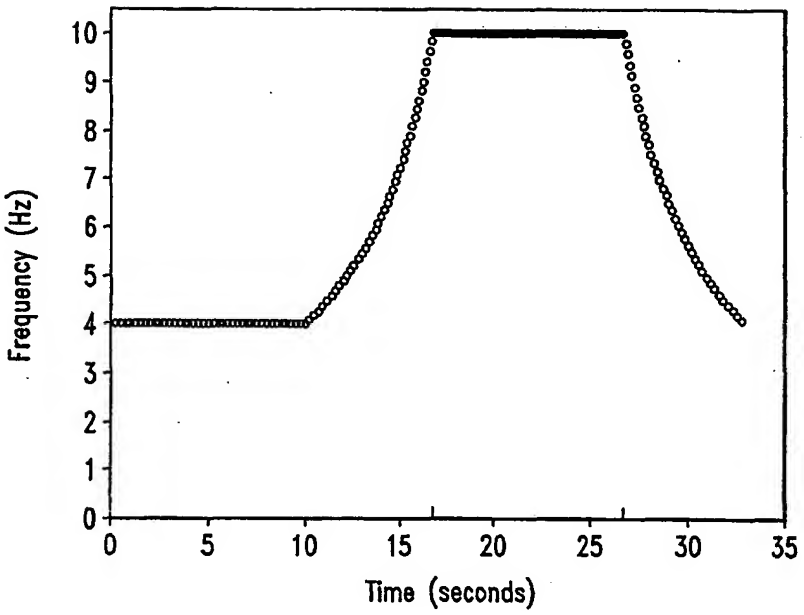

1210
AUTOMATICALLY VARY FREQUENCY
1212
RECEIVE SCHEDULE
MINIMUM FREQUENCY
MAXIMUM FREQUENCY
PERIOD
RATE OF CHANGE
1214
DIRECT VARIATION OF SIGNAL FREQUENCY OVER PERIOD
1216
LAST PERIOD OF SESSION?
NO
YES
END

Fig. 12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2
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8
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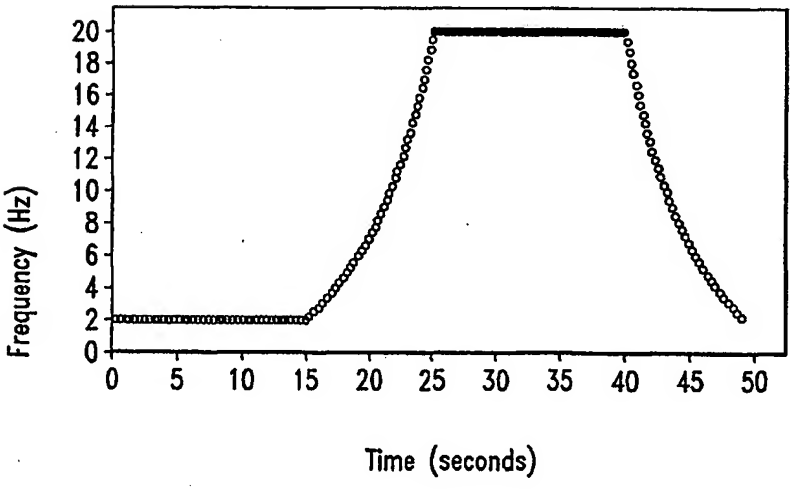
15
20
25
30
35
Time (seconds)

Fig. 13


Frequency (Hz)
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4
6
8
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18
20
0
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10
15
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25
30
35
40
45
50
Time (seconds)

Fig. 14

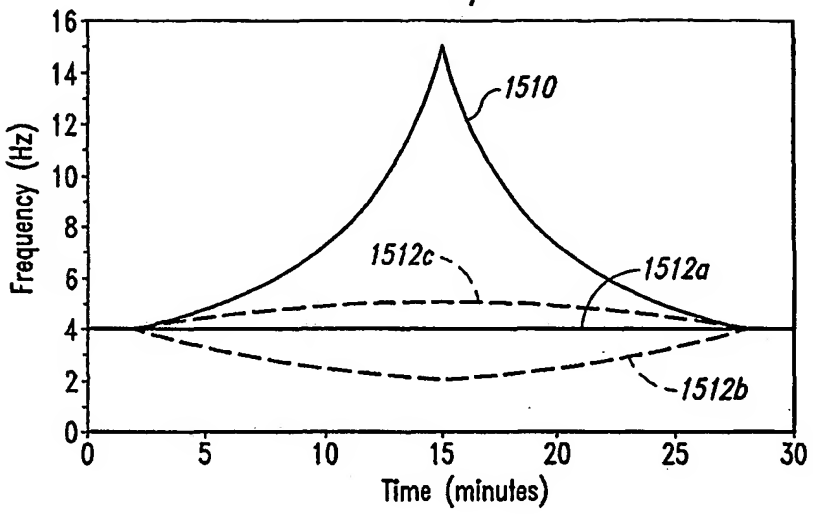

Fig. 15

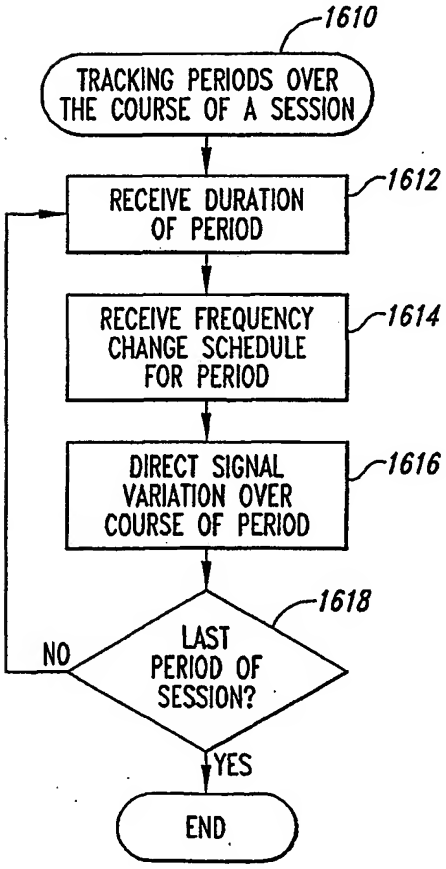

Fig. 16

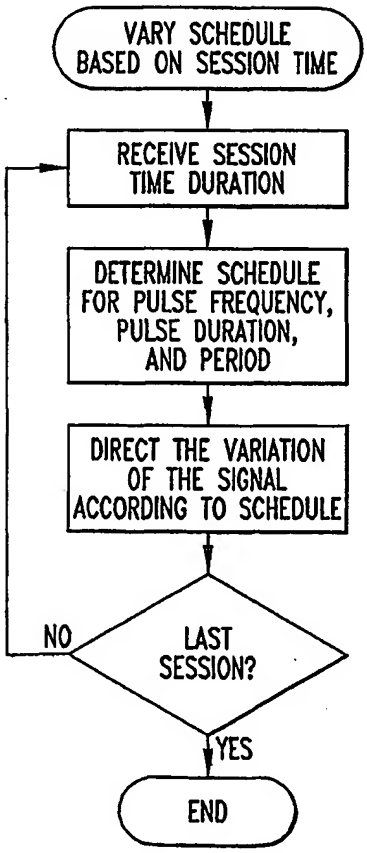

Fig. 17

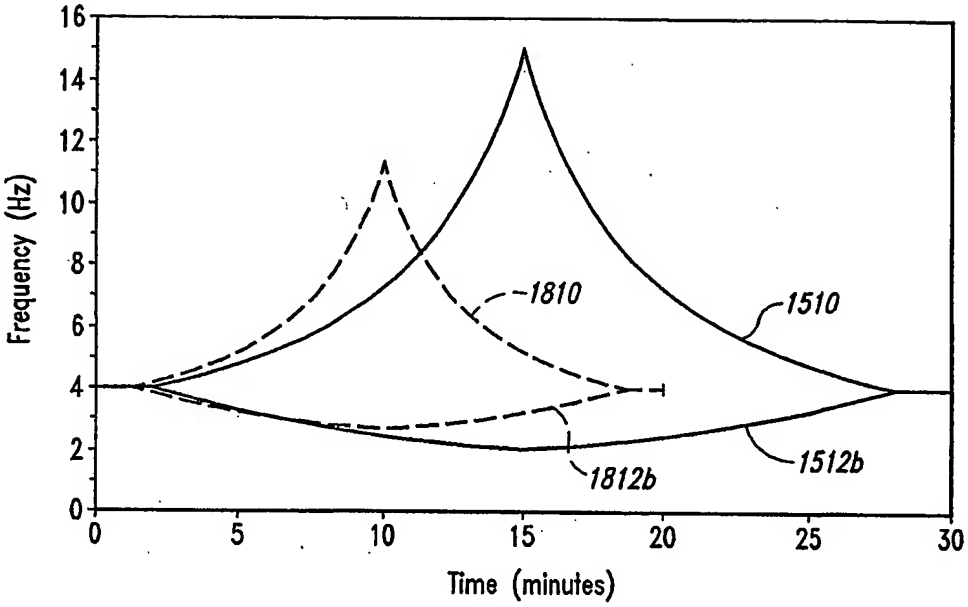
16
14
12
10
8
6
4
2
0
Frequency (Hz)
0
5
10
15
20
25
30
Time (minutes)
1810
1510
1812b
1512b

Fig. 18

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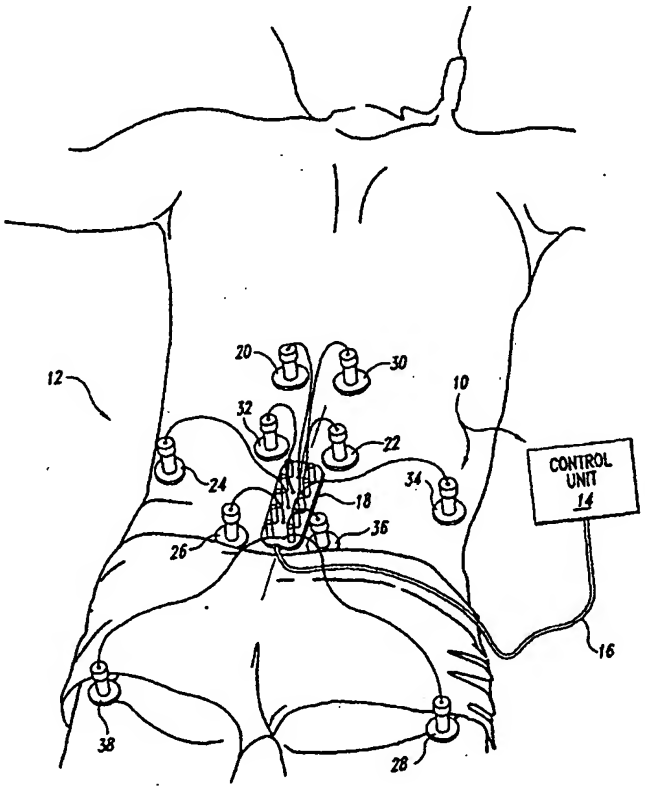
[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR VARYING CHARACTERISTICS OF ELECTRICAL THERAPY



(57) Abstract: A system and method for providing electrical nerve stimulation therapy to a recipient. A system in accordance with one embodiment to the invention can include electrode means (such as a percutaneous electrode) coupleable to a recipient. The system can further included signal generating means for applying an electrical signal to the electrode means. The signal generating means can include frequency varying means for applying the electrical signal to the electrode means at a plurality of frequencies.

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INTERNATIONAL SEARCH REPORT

Inte. ional Application No
PCT/US 01/31441

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 163 355 A (SIMONIN PHILIPPE PAUL HENRI) 26 February 1986 (1986-02-26)	1,28,30, 31
A	page 1, line 84 -page 2, line 52; figures	2-5,29
X	US 4 556 064 A (POMERANZ BRUCE ET AL) 3 December 1985 (1985-12-03)	28,29
A	column 6, line 9 -column 8, line 42; figures	1-4,12, 13,30, 32,33, 37,40
X	GB 2 255 719 A (MATTHEWS TONY) 18 November 1992 (1992-11-18)	28,29,35
A	page 1, line 30 -page 3, line 28; figures	1-6,33, 46

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 April 2002	07/05/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Rakotondrajaona, C

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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